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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,479	12/19/2006	Masayoshi Shichiri	4439-4047	9587

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
06/10/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ptopatentcommunication@lockelord.com

Office Action Summary	Application No.	Applicant(s)	
	10/599,479	SHICHIRI, MASAYOSHI	
	Examiner	Art Unit	
	CHIH-MIN KAM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *10,11 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 12-14* is/are rejected.

7)☒ Claim(s) *6-9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/06/06; 1/5/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1, 2, 5 and 12-14 in the response to restriction requirement filed March 27, 2009 is acknowledged. The traversal is on the ground(s) that at least Group I (claims 1, 2, 5 and 12-14) should be examined for the merits together with Group II (Claims 3, 4 and 6-9) according to Rule 13.1 PCT, which states Rule 13.1 is fulfilled when there is a technical relationship among those inventions involving one or more of the same corresponding technical features, and Example 39 of Chapter 10, paragraph 59 in the PCT International Search and Preliminary Examination Guidelines illustrates this analogous situation. Thus, the claims of Group I and II satisfy the unity of invention requirement. Applicants' response has been considered, and the arguments are found persuasive, thus Group II claims are rejoined with Group I claims. Therefore, claims 1-9 and 12-14 are examined.

Informalities

The disclosure is objected to because of the following informalities:

2. The abstract is objected to because it recites the amino acid sequence of SEQ ID NO:2 without providing the sequence identifier "SEQ ID NO:2". Appropriate correction is required.

3. The specification indicates a few amino acids are deleted in the sequence of SEQ ID NO:2, for example, 4 amino acid sequence at C-terminal are deleted (residues 5-24; page 11, lines 9-10), which is not correct. It should be 4 amino acid sequence at N-terminal are deleted, if the sequence is from residue 5 to residue 24. Appropriate correction is required.

Claim Objections

4. Claims 6-9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 6-9 have not been further treated on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is directed to a peptide or a DNA. As written, the claim does not explicitly indicate the hand of man. Insertion of "isolated or purified" in connection with the peptide or DNA is suggested. See MPEP § 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-5 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-5 and 12-14 are drawn to a peptide consisting of the following: the amino acid sequence shown by SEQ ID NO: 2; an amino acid sequence wherein one or a few amino acids

are deleted, substituted or added in the sequence shown by SEQ ID NO: 2, wherein a peptide consisting of the amino acid sequence has a cardioinhibitory activity or hypotensive activity; and an amino acid sequence having 60% or more homology with the amino acid sequence shown by SEQ ID No: 2, wherein a peptide consisting of the amino acid sequence has a cardioinhibitory activity or hypotensive activity; a DNA consisting of the following: a DNA encoding the peptide; a DNA consisting of the nucleotide sequence shown by SEQ ID NO: 1; a DNA encoding a peptide consisting of a nucleotide sequence wherein one or a few nucleotides are deleted, substituted or added in the sequence shown by SEQ ID NO: 1, and having a cardioinhibitory activity or hypotensive activity; and a DNA that hybridizes with the nucleotide sequence shown by SEQ ID NO: 1 under a stringent condition, and encoding a peptide having a cardioinhibitory activity or hypotensive activity; a method of screening a cardioinhibitory factor or hypotensive factor; a method of screening an inhibitor of a cardioinhibitory activity or an inhibitor of hypotensive factor; and a cardioinhibitory /hypotensive agent comprising the peptide.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or

by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

While the specification indicates that the present invention relates to a peptide consisting of the amino acid sequence of SEQ ID NO:2 and an amino acid sequence related to SEQ ID NO:2; a DNA encoding a peptide of SEQ ID NO:2 and an amino acid sequence related to SEQ ID NO:2; a DNA consisting of the nucleotide sequence of SEQ ID NO:1 and a nucleotide sequence related to SEQ ID NO:1 (paragraphs [0009], [0010]), the specification does not sufficiently describe a genus of variants for the amino acid sequences related to SEQ ID NO:2, or a genus of variants for the nucleotide sequences related to SEQ ID NO:1, when there is substantial variation within the whole genus of peptides or nucleotides. Although the specification discloses specific peptide fragments of SEQ ID NO:2 such as residues 1-20, 5-24 and 2-13 of SEQ ID NO:2 that are functional (paragraph [0014]), there is no structure-activity correlation for the variants or fragments of SEQ ID NO:1 or 2, a skilled artisan cannot predict which variant or fragment is functional. Furthermore, the specification does not identify or describe any DNA that hybridizes with the nucleotide sequence of SEQ ID NO:1 under stringent condition and encoding a functional peptide. A few species of SEQ ID NO:2 or 1 (e.g., full length and residues 1-20, 5-24 and 2-13 of SEQ ID NO:2; full length of SEQ ID NO:1) does not provide sufficient written description for the whole genus of variants of SEQ ID NO:1 or 2. The lack of description on the structure-activity correlation for the peptide or nucleotide variants and

lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-5 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1-5 and 12-14 are indefinite because of the use of the term "a few amino acids" or "a few nucleotides". The term cited renders the claim indefinite, it is not clear what are the metes and bounds for the term. Claims 5 and 12-14 are included in the rejection for being dependent of a rejected claim and not correcting the deficiency of the claim from which they depend.

9. Claims 1-2 are indefinite because the claims contain two periods "." (e.g., at line 2 of claim 1 and at line 3 of claim 2), it is not clear whether the phrases following the first period is part of the claim.

10. Claim 3 is indefinite because of the use of the term "under a stringent condition". The term cited renders the claim indefinite, it is not clear under what conditions the hybridization and washing are carried out.

11. Claim 12 is indefinite because of the use of the term "32 hypotensive factor". The term cited renders the claim indefinite, it is not clear what the term means.

12. Claims 12-13 are indefinite as to how to determine the test substance is a cardioinhibitory factor or hypotensive factor, or an inhibitor of cardioinhibitory activity or an inhibitor of hypotensive activity by measuring the level of cardioinhibitory activity or hypotensive activity because it is not clear what substances are included in the control and in the testing sample for comparison.

Conclusion

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK

June 5, 2009